Lipicon®

Atorvastatin Calcium Trihydrate USP
Film Coated Tablet

DESCRIPTION

Lipicon® is a preparation of Atorvastatin, a synthetic lipid lowering agent. Atorvastatin is an inhibitor of 3-hydroxy-3-methyglutaryl-coenzyme A (HMG-CoA) reductase, This enzyme catalyses the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis. The drug lowers elevated total cholesterol (C), low density lipoprotein (LDL) cholesterol, apolipoprotein B(apo B), and triglycerides (TG) in patients with primary hypercholesterolemia and with mixed dyslipidemia.

INDICATIONS

Atorvastatin is indicated as an adjunct to diet to reduce elevated total-C, LDL-C, apo-B, and TG levels in patients with primary hypercholesterolemia (heterozygous familial and non-familial) and mixed lipidemia. Atorvastatin is also indicated to reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid lowering treatments (eg.,LDL aphorises) or if such treatments are unavailable.
Prior to initiating therapy with Atorvastatin, secondary causes for hypercholesterolemia(eg, poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemia, obstructive liver disease, other drug therapy, and alcoholism) should be identified and treated.

DOSAGE AND ADMINISTRATION

Atorvastatin can be administrated within the dosage range of 10 - 80 mg/day as a single daily dose. Atorvastatin can be taken at any time of the day, with or without food. Therapy should be individualised according to the target lipid levels, the recommended goal of therapy, and the patient's response. After initial and/or upon titration of Atorvastatin, lipid level should be re-analysed within 4 weeks and dosage adjusted according to the patient's response.
Renal disease has no influence on the plasma concentrations or on the LDL-C reduction of Atorvastatin; thus, no adjustment of the dose is required. Plasma concentrations of Atorvastatin are markedly increased in patients with chronic alcoholic liver disease (Childs-Pugh B). The benefits of therapy should be weighed against the risks when Atorvastatin is to be given to patients with hepatic insufficiency.

CONTRAINDICATIONS

The absolute contra-indications to the administration of Atorvastatin include active liver disease or unexplained persistent elevations of serum transaminases and hypersensitivity to any component of this medication.

USE IN PREGNANCY AND LACTATION

Cholesterol and other products of cholesterol biosynthesis are essential for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause foetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. Atorvastatin should be administered to women of child-bearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the patient becomes pregnant while taking this drug, therapy should be discontinued and the patient appraised of the potential hazard to the fetus.

PRECAUTIONS AND WARNINGS

Liver function tests should be performed before the initiation of treatment and periodically thereafter. Patients who develop increased transaminase levels should be monitored until the abnormalities resolve. If an increase in ALT or AST of > 3 times the upper limit of normal persist, reduction of dose or withdrawal of Atorvastatin is recommended. Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease.

Atorvastatin therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis, e.g. severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures.

DRUG INTERACTIONS

Based on experience with other HMG-CoA reductase inhibitors, caution should be exercised when atorvastatin is administered with inhibitors of cytochrome P450 3A4 (e.g. cyclosporin, macrolide antibiotics including erythromycin and azole antifungals or niacin).
Co-administration of an oral antacid suspension, containing magnesium and aluminium hydroxide, with Atorvastatin decreased Atorvastatin plasma concentrations approximately 35%, however, LDL-C reduction was not altered. Plasma concentrations of Atorvastatin were lower (approximately 25%) when cholestyramine was co-administered than when either drug was given alone. Co-administration of multiple doses of Atorvastatin and digoxin increased steady-state plasma digoxin concentrations by approximately 20%. Patients taking digoxin should be monitored appropriately.

ADVERSE REACTIONS

Atorvastatin is well-tolerated. Adverse reactions have usually been mild and transient. Less than 2 % of patients were discontinued from clinical trials due to side effects attributed to Atorvastatin. The most frequent (≥1%) adverse effects associated with Atorvastatin therapy in patients participating in controlled clinical studies were constipation, flatulence, dyspepsia, abdominal pain, headache, nausea, myalgia, asthenia, diarrhoea and insomnia. Atorvastatin can cause elevation in ALT/AST, alkaline phosphatase, GGT, bilirubin and creatine phosphokinase.

OVERDOSAGE

There is no specific treatment for Atorvastatin overdosage. If an overdose occur, the patient should be treated symptomatically, and supportive measures instituted as required. Due to extensive drug binding to plasma protiens, haemodialysis is not expected to significantly enhance Atorvastatin clearance.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Lipicon® 10 mg tablet:
Box containing 5 strips of 10 tablets each. Each Film coated tablet contains Atorvastatin Calcium Trihydrate USP equivalent to Atorvastatin 10 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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